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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,093	12/01/2003	Fahri Saatcioglu	50218/002004	4578

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BOSTON, MA 02110

EXAMINER
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RAWLINGS, STEPHEN L

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/726,093	<b>Applicant(s)</b> SAATCIOGLU, FAHRI	
	<b>Examiner</b> Stephen L. Rawlings, Ph.D.	<b>Art Unit</b> 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed December 1, 2003, is acknowledged and has been entered.
2. Claims 1-14 are pending in the application and are currently subject to restriction.

### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-14, insofar as the claims are drawn to a method for detecting a neoplastic cell in a sample, said method comprising determining the amount of a polypeptide comprising the sequence of SEQ ID NO: 10 in the sample, classified, for example, in class 435, subclass 7.23.

Group II. Claims 1-13, insofar as the claims are drawn to a method for detecting a neoplastic cell in a sample, said method comprising determining the amount of a polypeptide comprising the sequence of SEQ ID NO: 11 in the sample, classified, for example, in class 435, subclass 7.23.

Group I. Claims 1-13, insofar as the claims are drawn to a method for detecting a neoplastic cell in a sample, said method comprising determining the amount of a polypeptide comprising the sequence of SEQ ID NO: 14 in the sample, classified, for example, in class 435, subclass 7.23.

4. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-III are patentably distinct, since, although each is a processes for detecting a neoplastic cell in a sample, the inventions of Group I comprise determining the amount of a polypeptide comprising SEQ ID NO: 10 in a sample,

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whereas the inventions of Groups II and III comprise determining the amounts of a polypeptide comprising SEQ ID NO: 11 or SEQ ID NO: 14, respectively, in a sample. Thus, the processes are necessarily materially different processes comprising different process steps since, for example, the processes might use different antibodies that bind specifically to each of the different polypeptides to measure the amount of the polypeptides in the samples.

Because the inventions of Groups I-III are distinct for these reasons, the search required to examine claims directed to one of these inventions is not the same, nor is it coextensive with the search required to examine claims directed to the other. Moreover, the search required to examine claims directed to the invention of Group I would include a search of the relevant databases using SEQ ID NO: 10 as a query; in contrast, the searches required to examine claims directed to the inventions of Group II and III would include a search of the relevant databases using SEQ ID NO: 11 and SEQ ID NO: 14, respectively, as a query. Because SEQ ID NO: 10, SEQ ID NO: 11, and SEQ ID NO: 14 are relatively unique amino acid sequences, none of these searches would provide sufficient information regarding the novelty and nonobviousness of any of the other inventions, and consequently different searches would necessarily be performed to examine claims directed to each of the different inventions. Because different searches would have to be performed to examine claims directed to the inventions of Groups I-III, an examination of more than one would constitute a serious burden.

Since the inventions of Groups I-III have been shown to be patentably distinct, and because the examination of more than one could not be made without serious burden, it is proper to restrict each from the other. See MPEP § 803.

5. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, searching more than

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one invention encompassed by the claim would constitute a serious burden; therefore, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

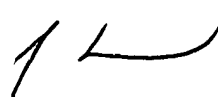
### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D., whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Stephen L. Rawlings, Ph.D.  
Examiner  
Art Unit 1643

slr  
May 31, 2006